Name: G-TL™
K133568

Vitrolife

JUL 16 2014

510(k) Summary

Submitted by:

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Date Prepared:

07/14/2014

Device Identification:

Trade Name:	G-TL™
Common Name:	IVF Media
Classification:	Class II Reproductive Media and Supplements (CRF 844.6180; Product Code MQL)

Predicate Device: CSC™ Complete (K121572)

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Description of the device:

G-TL™ is an aseptically filtered and manufactured bicarbonate-buffered physiological medium ready to use after warming to 37°C and equilibration in a CO_2 environment. It is designed to be used by professionals within assisted reproduction. G-TL™ is intended for the culture of human embryos from fertilization to the time of embryo transfer. G-TL™ is contained within a 30ml transparent polyethyleneterephthalate glycol (PETG) bottle with high density polyethylene (HDPE) closures. Both the bottle and box are individually labeled and each box contains a package insert.

Indication for Use:

G-TL™ is a medium for culture of embryos from fertilization to blastocyst stage.

Technical Characteristics:

CSC™ Complete and G-TL™ are aseptically filtered, physiological salt solutions containing pharmaceutical grade Gentamicin as an antibacterial agent and therapeutic human serum albumin (HSA). The predicate and new device are bicarbonate-buffered media for human embryo culture and are ready to use after warming to 37 °C and equilibration in a CO_2 environment. The predicate and new device have the same sterility level (SAL 10^{-3}), endotoxin level (<0.25 EU/ml), mouse embryo assay (≥80% expanded blastocyst on day 5) and storage conditions (store dark at +2 to 8°C). Physical specifications (pH and osmolality) are in the same physiological range for the predicate and new device (see Table 1). The indications for use are also the same as CSC™ Complete is a culture medium for human gametes and embryos from fertilization through day 5/6 of development in vitro.

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Table 1. Specifications of predicate and new device		
	CSC™ Complete	**G-TL™**
	K121572	**K133568**
pH	7.25-7.54	7.30 ±0.1
Osmolality (mOsm/Kg)	265 ±5	270 ±5
SAL	10^{-3}	10^{-3}
Bacterial endotoxin (EU/ml)	<0.25	<0.25
Mouse embryo assay (% expanded blastocyst on Day 5)	≥80	≥80
Storage conditions	Store dark +2 to 8°C	Store dark +2 to 8°C

The technological characteristics, specifications and indications of use for G-TL™ are comparable to those of the predicate device. Thus, there are no concerns with regards to substantial equivalence or safety and efficacy.

There are six chemical composition differences when comparing CSC™ Complete to G-TL™ (see Table 2).

- Taurine is a derivative of the amino acid cysteine and is present in G-TL™. Taurine is present in 510(k) cleared devices for embryo culture from day 1-5 (Early Cleavage Medium® K033462 and MultiBlast Media™ K034063: Irvine Scientific).

- G-TL™ contains a macromolecule named hyaluronan. Hyaluronan is widely distributed throughout tissues and is the major glycosaminoglycan present in follicular, oviductal and uterine fluid. Hyaluronan has been included in Vitrolife's Sequential Media for *in vitro* embryo culture G-1™/G-2™ version 3 (K022244 and K021890) since 2005 and continued with G-1™/G-2™ v5 (K081114 and K081117).

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- Four vitamins (calcium pantothenate, pyridoxine, thiamine and riboflavin) are present in G-TL™. Vitamins have been included in Vitrolife's media (K021890 and K081117) and are also found in Origio's EmbryoAssist (K080473) and BlastAssist (K080172) Orgio.

The differences in composition do not affect substantial equivalence and raise no concerns regarding safety and efficacy. Furthermore, animal studies during product development demonstrate that G-TL™ is substantially equivalent to the predicate device.

Table 2 Chemical composition		
	CSC™ Complete	**G-TL™**
	K121572	**K133568**
Sodium Chloride	X	X
Potassium Chloride	X	X
Calcium Chloride	X	X
Magnesium Sulfate	X	X
Sodium/Potassium Phosphate	X	X
Sodium Bicarbonate	X	X
Sodium pyruvate	X	X
Glucose	X	X
Sodium L- lactate	X	X
EDTA	X	X
Sodium Citrate	X	X

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Taurine	-	X
Alanyl glutamine	X	X
Gentamicin	X	X
Hyaluronan (sodium hyaluronate)	-	X
Non-essential amino acids	X	X
Essential amino acids	X	X
Vitamins	-	X

Performance data

The shelf life of G-TL has been validated in stability studies measuring the specifications to 21 weeks.

G-TL™ was compared to CSC™ Complete using the one-cell mouse embryo assay (MEA). There were no differences in embryo development or viability. Therefore, G-TL is considered substantially equivalent to the predicate device CSC™ Complete (K121572).

Conclusions:

The data demonstrates that the new device (G-TL™) is as safe and effective as the predicate device. The data also supports the determination of substantial equivalence between the predicate and new device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 16, 2014

Vitrolife, Inc.
Mark Larman, Ph.D.
Senior Scientist
3601 S. Inca Street
Englewood, CO 80110

Re: K133568
Trade/Device Name: G-TL™
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: June 18, 2014
Received: June 19, 2014

Dear Mark Larman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301)796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133568

Device Name
G-TL

Indications for Use *(Describe)*
Medium for culture of embryos from fertilization to blastocyst stage

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
2014.07.16 18:28:02 -04'00'

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